(heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5570 Lactoferrin immunological test system.

(a) *Identification*. A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, breast milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5580 *Alpha*-1-lipoprotein immunological test system.

(a) *Identification*. An *alpha*-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-1-lipoprotein (high-density lipoprotein) in serum and plasma. Measurement of *alpha*-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(b) *Classification*. Class II (performance standards).

§ 866.5590 Lipoprotein X immunological test system.

(a) *Identification*. A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 866.5600 Low-density lipoprotein immunological test system.

(a) *Identification*. A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

(b) *Classification*. Class II (performance standards).

§ 866.5620 *Alpha*-2-macroglobulin immunological test system.

(a) *Identification*. An *alpha*-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-2-macroglobulin (a serum protein) in plasma. Measurement of *alpha*-2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

(b) *Classification*. Class II (performance standards).

§ 866.5630 *Beta*-2-microglobulin immunological test system.

(a) *Identification*. A *beta*-2-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques *beta*-2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of *beta*-2-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

(b) *Classification*. Class II (performance standards).

§ 866.5640 Infectious mononucleosis immunological test system.

(a) *Identification*. An infectious mononucleosis immunological test system is

a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

(b) *Classification.* Class II (performance standards).

[47 FR 50823, Nov. 9, 1982; 47 FR 56846, Dec. 21, 1982]

§ 866.5660 Multiple autoantibodies immunological test system.

(a) *Identification.* A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in serum and other body fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (disease produced when the body's own tissues are injured by autoantibodies).

(b) *Classification.* Class II (performance standards).

§ 866.5680 Myoglobin immunological test system.

(a) *Identification.* A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart or renal disease.

(b) *Classification.* Class II (performance standards).

§ 866.5700 Whole human plasma or serum immunological test system.

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in plasma or serum. Measurements of proteins in plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

§ 866.5715 Plasminogen immunological test system.

(a) *Identification.* A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, other body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 866.5735 Prothrombin immunological test system.

(a) *Identification.* A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of blood-clotting disorders.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9. This exemption does not apply to multipurpose systems for in vitro coagulation studies classified under § 864.5425 of this chapter or prothrombin time tests classified under § 864.7750 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2313, Jan. 14, 2000]